Technology Assessment Program
Office of Patient Care Services

Bibliography UPDATE: Hyperbaric Oxygen Therapy for Traumatic Brain Injury and Post Traumatic Stress Disorder

*Selected, quality filtered, not subject to external review

Policy Issue: Traumatic brain injury (TBI) and post traumatic stress disorder (PTSD) are signature injuries among Veterans of Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF). Hyperbaric oxygen (HBO2) has been used to treat certain injuries (e.g., dive-related injuries, soft tissue injuries, carbon monoxide poisoning). Recently, it has been proposed as treatment for individuals with TBI or PTSD.

In August 2009, increasing interest in HBO2 for treatment of TBI prompted the Principle Deputy Under Secretary for Health to request a review by the Technology Assessment Advisory Group (TAAG) within the VA Office of Patient Care Services. The TAAG provides unbiased, evidence-based advice and recommendations for new healthcare technologies used in VA. The TAAG considers input from several sources such as the VA Technology Assessment Program (TAP), Clinical Expert Panels (CEPs) and a Utilization and Cost Analysis (UCA).

In January 2010, the Secretary of Veterans Affairs requested an updated review of the research on HBO2 for treatment of PTSD to support definitive VA policy. The purpose of this report is to provide the TAAG with a catalogue of published, peer-reviewed evidence on the appropriate clinical use of HBO2 for the Veteran population for treatment of TBI or PTSD.

Regulation and reimbursement: The US Food and Drug Administration (FDA) classifies a hyperbaric chamber as a prescriptive Class 2 device that is intended to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to a patient's tissue by means of pressurization that is greater than atmospheric pressure; this device does not include topical oxygen chambers for extremities (21CFR878.5650). Manufacturers of hyperbaric chambers are required to submit a Premarket Notification [510(k)] verifying the safety of the device and its intended prescribed uses. FDA requires investigational new drug (IND) registration of HBO2 for research purposes. FDA categorizes HBO2 as "more than minimal risk"; there is a 1:3000 risk of provoked seizures and small risk of fire/explosion.

FDA-approved indications are listed in Table 1. Historically, these indications have been adopted from the Hyperbaric Oxygen Therapy Committee Report produced by the Undersea & Hyperbaric Medical Society.[1]

The US Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) limits reimbursement for HBO2 therapy to that which is administered in a chamber (including the one man unit) for the indications listed in Table 1.[2] CMS does not authorize HBO2 as standard of care for TBI or PTSD, nor is it a reimbursable benefit for civilian providers by other third party payers.[3]

[1] http://www.uhms.org/Default.aspx?tabid=270 accessed September 3, 2009.
[2] http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=20.29&ncd_version=3&basket=ncd%3A20%2E29%3A3%3AHyperbaric+Oxygen+Therapy accessed September 8, 2009. National Coverage Decision 20.29.
[3] Raman G, Kupelnick B, Chew P, Lau J. A horizon scan: uses of hyperbaric oxygen therapy. *Rockville: Agency for Healthcare Research and Quality (AHRQ),* 2006:47.

Table 1. Regulation and reimbursement of HBO2

Indication	FDA-approved	CMS Covered
Air or Gas Embolism	√	√
Carbon Monoxide Poisoning or Carbon Monoxide Poisoning Complicated by Cyanide Poisoning	√	√
Clostridal Myositis and Myonecrosis (Gas Gangrene)	√	√
Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias	√	√
Decompression Sickness	√	√
Enhancement of Healing in Selected Problem Wounds	√	
Exceptional Blood Loss (Anemia)	√	
Intracranial Abscess	√	
Necrotizing Soft Tissue Infections	√	√
Osteomyelitis (Refractory)	√	√
Delayed Radiation Injury (Soft Tissue and Bony Necrosis)	√	√
Skin Grafts & Flaps (Compromised)	√	√
Thermal Burns	√	
Diabetic wounds of the lower extremities (Refractory)		√
Actinomycosis (Refractory)		√

Methods: To meet the client's urgent information needs, TAP sought the results of existing systematic reviews and health technology assessments (HTA) and supplemented them with updated searches of published primary data. In the case of TBI, results were confined to controlled clinical trials; in the case of PTSD, being a new indication for use, all research data were included.

On August 12, 2009, TAP searched Medline, Embase and Current Contents using the Dialog Information Service, the HTA database of the International Network of Agencies for Health Technology Assessment (INAHTA; www.inahta.org), and the Cochrane Library using search terms for hyperbaric oxygen crossed with search terms for brain or head injury, concussion, trauma or for military related citations. TAP applied an evidence filter to identify high quality publications types such as meta-analyses, systematic reviews, and evidence-based guidelines or recommendations published in English and which synthesize research with adult human subjects. TAP conducted a second search for controlled trials published subsequent to when the available systematic reviews had concluded their searches. On August 18, 2009 TAP queried members of the International Network of Agencies for HTA (INAHTA; www.inahta.org) through its electronic listserv for existing reports or reports in progress that were not listed in existing electronic databases. These results are presented in Table 4.

On January 25, 2010 TAP updated searches for TBI using the above strategy and retrieved seven additional citations. TAP expanded its searches to include indications for PTSD (See Appendix). After first searching The Cochrane Library with no results, searches were done in 13 biomedical/health /life sciences/clinical databases available through the Dialog Information

Service. They were searched very broadly using a comprehensive list of terms indicating PTSD and were then combined with a list of hyperbaric oxygen treatment terms. Ultimately, this search retrieved 96 unique citations. TAP initiated another INAHTA query on January 25, 2010 for updated information regarding HBO2 treatment for either TBI or PTSD.

Results: Searches, review of end references of retrieved systematic reviews and responses from INAHTA members captured 220 citations, of which 43 were retrieved as potentially relevant to the report. An overview of the search results confirm a substantial body of research on the clinical uses of HBO2 as evidenced by the growing number of organizations involved in conducting health technology assessments (HTA) and systematic reviews on the subject.

HTAs and systematic reviews of HBO2 for TBI have emerged in recent years as the body of clinical research increases for this indication (See Tables 2 and 4). In addition to these reviews, results from one newly published controlled clinical trial was identified (Rockswold 2009).

For PTSD, no systematic reviews or HTAs were identified, and only one case report was identified reporting on the use of HBO2 in a young military Veteran with post-concussion syndrome and PTSD (Harch 2009; see end reference for abstract).

Ongoing clinical research is presented in Table 3.

Table 2. Summary of systematic reviews of HBO2 for TBI

Citation	Findings
Ritchie 2008	• Some evidence of reduced risk of death from TBI but little evidence of better functional outcome among survivors (based on Bennett 2004 and McDonagh 2004 and five new observational studies) • Adverse effects were poorly assessed
De Laet 2008	Very low quality evidence from small trials for a reduced risk of death, without evidence for improved outcomes in terms of quality of life (includes Bennett 2004)
Pichon-Riviere 2006	• Insufficient evidence (based on Bennett 2004) • Not recommended for clinical use
Bennett 2004 (Cochrane review)	• Limited evidence of reduced mortality or that survivors have improved quality of life
McDonagh 2003 (for AHRQ)	• Conflicting and inconclusive evidence of effectiveness • Potential small mortality benefit which may depend on subgroup selection • Effect on functional status and incidence and clinical significance of adverse effects are unclear
Oppel 2003	• Strongest evidence indicated either no effect or harm from HBO2 use • Use of HBO2 not supported
Avalia-t 2003	• Insufficient evidence (in Spanish)

Conclusions: Traumatic brain injury. The systematic reviews by McDonagh (2003) and Bennett (2004) provide the most rigorous and current information on the status of the clinical research for the use of HBO2 in TBI. Subsequent reviews identified these two reviews as the primary basis for their conclusions. To summarize their results, the clinical value of HBO2 in treating TBI is unknown due to insufficient evidence proving its effectiveness or ineffectiveness. Several case reports suggest positive outcomes for patients with TBI, but these studies were inconclusive for determining effectiveness as they were not randomized, controlled, or blinded

studies. Therefore, it is unknown whether individual case reports of recovery are due directly to HBO2 therapeutic benefit, or natural recovery of each individual. The degree to which placebo effect may account for both symptom and imaging improvement in delayed treatment reports remains unknown. Promising results from animal studies have not as yet translated to humans. High quality research is needed to determine clinical efficacy of HBO2 in TBI treatment.

TAP's updated searches uncovered one recently published Phase II trial (See Table 3 below; NCT00170352). This study assessed evaluated the use of HBO2 and 100% FiO2 (fraction of inspired oxygen delivered) separately and in combination compared with standard care in a cohort of ventilated subjects with an acute severe TBI (GCS score ≤ 8) within 24 hours of injury. Subjects received hyperoxia treatments every 24 hours for three treatment sessions. HBO2 delivered to achieve a brain tissue $P0_2$ > 200 mm Hg has a greater positive effect than normobaric hyperoxia therapy on oxidative cerebral metabolism and intracranial pressure. Effect was sustained for at least six hours post treatment over the course of three treatment sessions without pulmonary or cerebral oxygen toxicity. Results suggest hyperoxia treatment in subjects with early, severe TBI may be safe and efficacious, and several clinical trials are in progress that may help inform these results (see Table 3). However, improvement in mortality or morbidity over the long-term requires further study.

Conclusions: Post traumatic stress disorder. As only one case report was identified, the threshold for rigorous evidence of effectiveness for the treatment of PTSD with HBO2 has not been met. Existing evidence in the published research and popular press comprises anecdotes of promise and potential for this technology at times by proponents of HBO2 with financial and professional interests. Unbiased, independent research assessing the safety, feasibility and relative effectiveness of HBO2 is needed especially in a cohort of Veterans whose treatment options may otherwise be limited.

Ongoing research:

Table 3. Search results of ClinicalTrials.gov for "traumatic brain injury" OR "post traumatic stress" AND "hyperbaric" conducted September 11, 2009 and again January 25, 2010.

ClinicalTrials.gov Identifier	Title	Phase	Status
NCT00170352	Comparison Between Different Types of Oxygen Treatment Following Traumatic Brain Injury	II	Completed
NCT00594503	Hyperbaric Oxygen Therapy and SPECT Brain Imaging in Traumatic Brain Injury	I	Recruiting
NCT00715052	The Effect of Hyperbaric Oxygen Therapy on Patients Suffering From Neurologic Deficiency Due Traumatic Brain Injury	Not reported	Recruiting
NCT00760734	Pilot Study of Hyperbaric Oxygen Therapy (HBOT) in Chronic Traumatic Brain Injury (TBI)/Post Concussion Syndrome (PCS) and TBI/Post-Traumatic Stress Disorder (PTSD)	I	Recruiting
NCT00810615	Treatment of Traumatic Brain Injury With Hyperbaric Oxygen	I / II	Enrolling by invitation
NCT00830453	Hyperbaric Oxygen Therapy in Chronic Stable Brain Injury (HYBOBI)	II	Recruiting

VA and Department of Defense (DoD) are collaborating to improve the knowledge and use of HBOT in TBI. In 2008, the U.S. Navy Surgeon General convened a Steering Group of experts

from VA, DoD and academia, and tasked the Defense Center of Excellence (DCoE) for Psychological Health and TBI to lead efforts in determining the current scientific status of HBO2 in TBI. The Steering Group completed a comprehensive review of medical literature and convened a consensus conference in December 2008. They reviewed basic neuroscience of mild TBI/concussion, anecdotal reports of use, pilot studies and possible outcome measures.

The Steering Group concluded the following:

- At present, HBO2 cannot be accepted as standard-of-care for Service Members or Veterans with TBI.
- Exceptions to provide HBO2 for patients with TBI are currently offered on a limited case by case basis.
- HBO2 case reports are compelling enough to mandate expedited research trials.
- DoD and VA should conduct focused, expedited research of HBO2 in chronic, mild TBI via rigorous clinical trials to determine benefit.

From the consensus conference the Steering Group developed a research protocol from which DCoE is expediting a DoD-funded prospective clinical trial at four DoD facilities to investigate the efficacy of HBO2 for symptomatic, chronic mild and moderate TBI, with and without PTSD. This large, randomized, double-blinded, controlled multi-center study will be powered to be a definitive study (Phase 3) determining efficacy of HBO2 in chronic, mild and moderate TBI. Full study completion and outcome assessment of the entire cohort is projected by December 2010. A Data Safety Monitoring Board will begin to review preliminary results of data in the fall of 2009.

In addition, two Phase 2 DoD/VA studies are planned or underway:[4]

1. In January 2009, the Defense Advanced Research Projects Agency (DARPA) and the Telemedicine & Advanced Technology Research Center (TATRC) funded the Richmond VA Medical Center and Virginia Commonwealth University to perform a feasibility study: "Hyperbaric Oxygen Therapy for Post-Concussive Symptoms after mild Traumatic Brain Injury: A Randomized, Double-Blinded, Sham-Controlled, Variable Dose, Prospective Trial" (Dr. David Cifu, Principle Investigator, Richmond VAMC). The study will be in partnership with the Naval Operational Medicine Institute in Pensacola, FL and Quantico Marine Corp base (status: in planning stage).
2. An Air Force-sponsored double-blind pilot study (50 patients) began at Wilford Hall Medical Center in San Antonio, TX in February 2009 for use of HBO2 for mild TBI symptoms (See Table 3; NCT00810615). The study will provide safety and feasibility data regarding dose level. Results of this study are anticipated April 2010.

[4] **Contact for Further Information:** Dr. David Chandler, VHA Deputy Chief Consultant Rehabilitation Service (117) Tel: (202) 461-7353; e-mail: david.chandler2@va.gov.

Table 4. Relevant responses from INAHTA members of evaluations of HBO2 for TBI or PTSD

Agency	Response	Findings
AETMIS (Quebec, Canada)	AETMIS 2008 report: One of the indications is traumatic brain injury. French full text with English summary. Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). Indications de l'oxygénothérapie hyperbare: mise à jour. Rapport préparé par Guylaine Rouleau, Khalil Moqadem et Gilles Pineau. ETMIS 2008;4(5):1-94. http://www.aetmis.gouv.qc.ca/site/download.php?f=22d86c2275184efe905e168aedce0556 (English summary)	Insufficient evidence
AHRQ (USA)	2003 evidence report: McDonagh M, Carson S, Ash J, et al. Hyperbaric Oxygen Therapy for Brain Injury, Cerebral Palsy, and Stroke. Evidence Report/Technology Assessment No. 85 (Prepared by the Oregon Health & Science University Evidence-based Practice Center under Contract No 290-97-0018). AHRQ Publication No. 04-E003. Rockville, MD: Agency for Healthcare Research and Quality. September 2003. http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat1a.chapter.42064 2006 horizon scanning report included evidence above with same conclusions. http://www.cms.hhs.gov/determinationprocess/downloads/id42TA.pdf	Insufficient evidence Not covered by CMS
Avalia-t (Galicia, Spain)	2003 evidence report: Indicaciones de la oxigenoterapia hiperbárica. SERIE CONSULTAS TÉCNICAS CT2003/08/. Santiago de Compostela. Axencia de Avaliación de Tecnoloxías Sanitarias (avalia-t). Galicia, España. In Spanish.	Insufficient evidence
CADTH (Canada)	Citations forwarded to VATAP: Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.: CD004609. DOI: 10.1002/14651858.CD004609.pub2: http://www.cochrane.org/reviews/en/ab004609.html Hyperbaric Oxygen Therapy for Brain Injury, Cerebral Palsy, and Stroke AHRQ, 2003: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat1a.chapter.42064 In addition, patients are currently being recruited for a clinical trial on this topic: http://clinicaltrials.gov/ct2/show/NCT00830453 Hyperbaric Oxygen Therapy in Chronic Stable Brain Injury (HYBOBI). Phase II study. Salt Lake City, UT. ClinicalTrials.gov identifier NCT00830453. (actively recruiting; estimated completion Dec 2010). The purpose is to study the feasibility of conducting clinical research in individuals with chronic sequelae following brain injury who are given hyperbaric oxygen.	
ICES (Argentina)	See 2006 report: Pichon Riviere 2006. http://www.iecs.org.ar/iecs-visor-publicacion.php?cod_publicacion=389	Did not evaluate TBI or PTSD
ICTAHC (Israel)	The Effect of Hyperbaric Oxygen Therapy on Patients Suffering From Neurologic Deficiency Due Traumatic Brain Injury. Zerifin, Israel. Clinicaltrials.gov identifier: NCT00715052. (actively recruiting; estimated completion Jan 2010). The aim of the RCT is to evaluate the effect of HBO2 on patients with chronic neurologic deficiency due to TBI using clinical/cognitive tests and functional brain imaging with SPECT.	Encouraging interim results reported by principal investigator but no data available
IHE (Canada)	Report provided: *Hyperbaric oxygen therapy – recent findings on evidence for its effectiveness* published in 2003 by the Alberta Heritage Foundation for Medical Research. This report can also be accessed from the Institute of Health Economics website at: http://www.ihe.ca/documents/hyperbaric_oxygen_therapy.pdf.	PTSD not covered TBI—inconclusive
KCE (Belguim)	De Laet C, Obyn C, Ramaekers D, Van De Sande S, Neyt M. Hyperbaric Oxygen Therapy: a Rapid Assessment. Health Technology Assessment (HTA). Brussels: Belgian Health Care Knowledge Centre. (KCE); 2008. KCE	TBI—Insufficient PTSD not covered

Agency	Response	Findings
	Reports 74C (D/2008/10.273/15). Refer to section 3.4.16 'miscellaneous indications' for TBI. In part 3.4.9 evidence for the indication 'Post-anoxic encephalopathy' is also discussed. In English. Citation forwarded to VATAP: 'Bennett MH, Trytko B, Jonker B. Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. Cochrane Database of Systematic Reviews: Reviews 2004 Issue 4 John Wiley & Sons, Ltd Chichester, UK DOI: 10.1002/14651858.CD004609.pub2. 2004(4).'	
NHSQIS (Scotland)	Produced comprehensive systematic review on hyperbaric oxygen therapy in 2008. (http://www.nhshealthquality.org/nhsqis/4208.html) This was used by the Public Health Specialist Commissioners group in the UK to develop guidelines. Ritchie K, Baxter S, Craig J, Macpherson K, Mandava L, McIntosh H, Wilson S. The clinical and cost effectiveness of hyperbaric oxygen therapy. HTA programme: Systematic Review 2 - July 2008. http://www.nhshealthquality.org/nhsqis/files/ClinicalGovernance_ClinicalAndCostEffectivenessOfHBOT_OCT08.pdf	TBI—inconclusive PTSD not covered
SBU (Sweden)	Guidelines for the use of HBOT have been published by The Swedish society of anaesthesia and intensive care (www.sfai.se). HBOT is not used for treating traumatic brain injury.	Not used
ZonMW (The Neth.)	No clinical trials funded at this time. Another possible contact is the Institute of Hyperbaric Medicine in Holland, their site is: http://www.ivhg.nl/startpaginainsti.html Three locations are involved: info-rotterdam@ivhg.nl info@ivhg.nl info-arnhem@ivhg.nl	

APPENDIX

Dialog Information Services – Search strategy for PTSD and HBO2 – January 25, 2010
13 Databases Searched:

1. MEDLINE
2. EMBASE
3. Current Contents
4. PsycINFO
5. BIOSIS
6. CSA – Life Sciences
7. SCI-Search
8. Social SCI-Search
9. Global Health
10. Federal Research in Progress
11. Gale Group Health & Wellness
12. General Science Abstracts
13. NewsRx Weekly Reports

S STRESS DISORDERS, POST-TRAUMATIC?/DE OR POSTTRAUMATIC STRESS DISORDER?/DE

S PTSD/TI,AB,GS,KW,SH

S COMBAT(2N)NEUROS?/TI,DE OR COMBAT(2N)DISORDER?/TI,DE OR COMBAT(2N)FATIGUE?/TI,DE OR COMBAT(2N)PSYCHO?/TI,DE OR COMBAT(2N)PSYCHI?/TI,DE

S (POSTTRAUMATIC? OR POST()TRAUMATIC?)/TI,DE(1N)(STRESS? OR NEUROS? OR DISORDER? OR PSYCHIATR? OR PSYCHO? OR PSYCHIC?)/TI,DE

S (WAR()TIME OR WARTIME OR COMBAT OR OIF OR OEF OR WAR OR TORTUR??? ? OR DEPLOY? OR TERROR?)/TI,DE(2N)(STRESS? OR AFTERMATH? OR CONSEQUENCE? OR OUTCOME? OR SEQUEL? OR
AFTER()EFFECT? OR MENTAL()HEALTH OR MENTAL? OR PSYCHOSOCIAL? OR PSYCHO()SOCIAL? OR INTRUSIVE()MEMOR?)/TI,DE

S (WAR? ? OR TERROR? OR OIF OR OEF OR COMBAT OR IRAQ OR AFGHAN? OR DEPLOY? OR RE()DEPLOY?)/TI,DE

S S1 OR S2 OR S3 OR S4 OR S5 OR S6
S NOT HUMAN? ?/DE,GS

RESULTS COMBINED WITH HYPERBARIC TERMS –

S HYPERBARIC?(N)OXYGEN?/TI,DE
S OXYGEN?(N)HYPERBARIC/TI,DE OR HIGH()(TENSION? OR PRESSUR?)()OXYGEN?/TI
S HYPERBARIC?(N)REOXYGEN?/TI,DE

YIELDING - 95 unique citations, of these 1 case report directly relevant.

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Bennett Michael H, Trytko B, Jonker B. Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. *Cochrane Database of Systematic Reviews,* 2004(4). Art. No.: CD004609. DOI: 10.1002/14651858.CD004609.pub2: http://www.cochrane.org/reviews/en/ab004609.html

De Laet C, Obyn C, Ramaekers D, et al. Hyperbaric Oxygen Therapy: a Rapid Assessment KCE Report 74C. *Belgian Health Care Knowledge Centre, Health Technology Assessment (HTA)* 2008:130.

Harch PG, Fogarty EF, Staab PK, Van Meter K. Low pressure hyperbaric oxygen therapy and SPECT brain imaging in the treatment of blast-induced chronic traumatic brain injury (post-concussion syndrome) and post traumatic stress disorder: a case report. *Cases Journal,* 2009; 2: 6538. A 25-year-old male military veteran presented with diagnoses of post concussion syndrome and post traumatic stress disorder three years after loss of consciousness from an explosion in combat. The patient underwent single photon emission computed tomography brain blood flow imaging before and after a block of thirty-nine 1.5 atmospheres absolute hyperbaric oxygen treatments. The patient experienced a permanent marked improvement in his post-concussive symptoms, physical exam findings, and brain blood flow. In addition, he experienced a complete resolution of post-traumatic stress disorder symptoms. After treatment he became and has remained employed for eight consecutive months. This case suggests a novel treatment for the combined diagnoses of blast-induced post-concussion syndrome and post-traumatic stress disorder.

McDonagh M, Carson S, Ash J, et al. Hyperbaric oxygen therapy for brain injury, cerebral palsy, and stroke. *Evidence Report/Technology Assessment*, 2003 (85): 1-6.

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Report released: January 2010